Docket No.: 511582002500
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Patent Application of:
Pia M. CHALLITA-EID et al.

Application No.: 10/024,652

Filed: December 17, 2001

For: NUCLEIC ACID AND ENCODED ZINC TRANSPORTER PROTEIN ENTITLED 108P5H8 USEFUL IN TREATMENT AND DETECTION OF CANCER

Confirmation No.: 2714

Examiner: B. Bunner

Art Unit: 1647

REPLY BRIEF

MS Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Appellants file this Reply Brief to Examiner's Answer pursuant to the provisions of 37 C.F.R. § 41.41 in connection with the above-identified application. The Examiner's Answer was mailed on March 7, 2007. Thus, according to 37 C.F.R. § 1.193, a Reply Brief must be filed within two months from the mailing of the Examiner's Answer, May 7, 2007. As such, this Reply Brief is timely filed.

Applicants do not wish to avail themselves of their right to an oral hearing. As such, Applicants request that the present appeal be decided on the papers alone.

Claims 4, 6-7, 9, 10, 12, 13, 78, and 80-83 of the present application stand rejected under 35 U.S.C. § 101, because the claimed invention allegedly is not supported by either a credible, specific and substantial asserted utility, or a well established utility. A companion rejection of the claims under 35 U.S.C. § 112, first paragraph for allegedly lacking enablement has also been made. Appellants respectfully request the Board reverse these rejections because the Examiner has misapplied the test for utility as it relates to the pending claims.

Argument

The Board should reverse the final rejection of pending claims 4, 6-7, 9, 10, 12, 13, 78, and 80-83 for an alleged lack of utility because the Examiner has misapplied the test for utility. The Examiner has misunderstood the meaning of the terms "specific" and "substantial" as they relate to the question of utility. Moreover, the Examiner has failed to recognize that the evidence provided during prosecution is sufficient to demonstrate that the claimed subject matter functions in accordance with the asserted utility. In view of this, the Board should overturn the present rejections and instruct the Examiner to issue the pending claims.

The Pending Claims Satisfy the Utility Standard

The specification as filed in addition to the evidence provided during prosecution amply demonstrates the usefulness of the claimed invention. At the outset Applicants note that it is the examiner who must meet the initial burden of showing that a claimed invention lacks patentable utility. *See In re Brana*, 51 F.3d 1560, 1566 (Fed. Cir. 1995). ("Only after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence.")

The Supreme Court addressed section 101's utility requirement in *Brenner v. Manson*, 383 U.S. 519 (1966). The *Brenner* Court held that "[t]he basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point—where specific benefit exists in currently available form—there is insufficient justification for permitting an applicant to engross what may prove to be a broad field." *Id.* at 534-35.

The predecessor of the Federal Circuit, the Court of Customs and Patent Appeals (CCPA), applied the Supreme Court's guidance provided in *Brenner* in *In re Kirk*, 376 F.2d 936 (CCPA 1967). The invention in *Kirk* related to steroid derivatives whose asserted utility was as a source of continued research. *Id.* at 938. The court found this asserted utility to be insufficient to satisfy the statute. "There can be no doubt that the insubstantial, superficial nature of vague, general disclosures or arguments of 'useful in research' or 'useful as building blocks of value to the researcher' was recognized, and clearly rejected, by the Supreme Court" in *Brenner*. *Kirk* at 945.

The Federal Circuit held that section 101 was not satisfied in an application for a patent reciting that "solid granules of polypropylene could be pressed into a flexible film with a characteristic infrared spectrum and that the polypropylene was 'plastic-like.'" *In re Ziegler*, 992 F.2d 1197, 1203 (Fed. Cir. 1993). "Ziegler did not assert any practical use for the polypropylene or its film, and Ziegler did not disclose any characteristics of the polypropylene or its film that demonstrated its utility." *Id.* "[A]t best, Ziegler was on the way to discovering a practical utility for polypropylene at the time of the filing." *Id.*

The CCPA reversed a lack of utility rejection in *In re Jolles*, 628 F.2d 1322 (CCPA 1980), where the claimed compositions were asserted as being useful for the treatment of acute myeloblastic leukemia. The claimed components of the composition were related to compounds that were "recognized in the art as valuable for use in cancer therapy" and the evidence showed that the claimed compounds were effective in treating tumors in a mouse model. *See id.* at 1323-23.

With respect to section 101's requirement that an invention be "useful", the term requires a use that is "substantial," that is, a use that provides a specific benefit in currently available form. *Id.* This availability can be demonstrated by showing that the invention functions in accordance with the asserted utility. By contrast, "vague, general disclosures or arguments of 'useful in research' or 'useful as building blocks of value to the researcher'" do not satisfy section 101 (*Kirk*).

In the present case the Examiner has taken the position that the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility. Examiner's Answer, page 3. The Examiner has provided no evidence to support this position, only

argument. In contrast, Applicants have demonstrated that the claimed invention functions as asserted.

The Pending Claims are Supported by a Specific and Substantial Utility

Applicants have repeatedly asserted that the claimed antibodies are useful as a therapeutic agent for treating prostate cancer. This asserted utility is supported by the fact that the protein to which the antibodies bind is expressed on cancerous prostate cells. This expression has been demonstrated by the detection of mRNA encoding the protein, as well as by evidence that polyclonal antibodies made against the protein have been shown to bind to cancerous prostate tissue samples. Notwithstanding this evidence, the Examiner maintains that the asserted utility is neither credible, specific and substantial nor is it well established. The Examiner is in error.

The Examiner alleged during prosecution and in the Examiner's Answer that the claimed invention was not credible. *Id.* at page 3 and page 16. However, the Examiner also admitted that "[t]he truth, or credibility, of the assertion of utility has not been questioned. Rather, the rejection sets forth that the assertion of utility is not specific or substantial." *Id.* at page 12. In view of this admission, it is Applicant's admission that the present rejections rest solely on the allegation that the pending claims lack a "specific" and "substantial" utility.

It is apparent from the record that the Examiner misapprehends the meaning of the terms "specific" and "substantial." The presently claimed subject matter is useful for the treatment of prostate cancer. This asserted utility is not generic, as would an assertion that the 108P5H8 protein is useful to treat diseases, but instead specific for prostate cancer. The specificity of this asserted utility satisfies the statutory requirement.

The Examiner would have the Board believe that the 108P5H8 protein is just like any other cell surface protein, of which there are many. But Applicants have demonstrated that the 108P5H8 protein is expressed on cancerous prostate cells and therefore is useful as a therapeutic target for antibody-mediated prostate cancer therapy. The Examiner alleged that there is nothing about the 108P5H8 protein that sets it apart from any other cell surface protein. This allegation is simply incorrect. As shown in the specification, for example in Figure 11, the 108P5H8 protein is not ubiquitously expressed in all normal tissues, but instead is expressed in a very restricted number of

tissues, including prostate cells. The limited expression pattern of the protein taken with the observation that the protein itself is detectable on cancerous prostate cancer cells is more than adequate evidence to demonstrate the usefulness of the claimed invention as a prostate cancer therapy.

The Examiner acknowledged that other targets of antibody therapy are expressed in normal as well as cancerous tissue. Nevertheless, the Examiner persists in the argument that because the biological function of the 108P5H8 protein is not well understood, the pending claims lack utility. Again, the Examiner misunderstands the nature of the utility requirement. The purpose of this portion of the statute is to ensure that patents are granted for useful subject matter. It is completely irrelevant what biological role the 108P5H8 protein plays in the life of a cell. All that matters, for the purposes of patentability, it that the protein be expressed on prostate cancer cells and that the protein be detectable by antibodies made against that protein. Applicants have clearly demonstrated both of these features for the claimed subject matter. As such, although the burden of alleging lack of utility falls squarely on the Examiner, Applicants have clearly demonstrated the specific and substantial utility of the claimed subject matter.

The asserted use for the claimed antibodies as a therapeutic agent for treating prostate cancer is substantial as it is immediately available for use without requiring additional experimentation. The Examiner appears to be of the opinion that an invention is not eligible for patenting unless it is ready for approval by the Food and Drug Administration. Fortunately, this is not the standard for patentability. *In re Brana* at 1567. There is nothing in the record or in the art as a whole that would lead one of ordinary skill in the art that the presently claimed invention lacked a substantial utility. As discussed above, other anti-tumor antibodies cross-react with normal tissue and yet are effective in the treatment of cancer. As such, this criticism is insufficient to support a lack of utility rejection. In view of the data provided in the specification as well as the art-recognized need for additional prostate cancer markers, Applicants submit that the specification clearly asserts a substantial utility for the claimed invention.

As stated in the Appeal Brief, it appears to Applicants that the heart of the Examiner's allegation that the claimed antibodies lack utility lies with the observation that Applicants have not

provided any evidence that the target protein 108P5H8 is overexpressed in cancer cells as compared to normal cells. Contrary to the Examiner's position, overexpression of the target protein on prostate cancer cells versus normal cancer cells is not necessary for the claimed antibodies to be useful as a therapeutic agent. This is because the prostate is a disposable organ, so the claimed antibodies need not be able to differentiate between normal and cancerous prostate cells to be useful. Thus, the presence or absence of differential expression is not relevant to the question of utility for the claimed invention.

Overexpression of the target protein is not required for the claimed antibodies to be useful as a therapeutic because the prostate is a disposable organ. If a patient has cancer in an organ that is essential for life, say liver cancer for example, then ideally the cancer therapy used to treat the patient will not unnecessarily target non-cancerous tissue. A therapy that indiscriminately targets normal tissue would likely to cause more harm than good. However, the prostate is not an essential organ. It is disposable and a human male can live without a functioning prostate. In view of the disposable nature of the prostate, it is not necessary to demonstrate overexpression of the target protein in cancerous prostate cells to demonstrate that the claimed antibodies are useful. All that is required to show that the claimed antibodies will, more likely than not, function as a useful treatment for prostate cancer, is a demonstration that the 108P5H8 protein is expressed on the surface of prostate cancer cells and that the protein can be detected by antibodies made against the protein. Applicants have provided this data.

CONCLUSION

The threshold of utility is not high under 35 U.S.C. § 101; an invention is useful if it is merely capable of providing some identifiable benefit. *Juicy Whip, Inc. v. Orange Bang, Inc.*, 51 U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999) (*citing Brenner v. Manson*, 383 U.S. 519, 534 (1966)). Applicants have satisfied the statutory requirement for demonstrating that the claimed invention is useful. Evidence supporting the utility of the invention is present both in the specification as filed as well as in the prosecution history. The evidence proffered is more than adequate to support the utility asserted by Applicants. As such, the Board is respectfully requested to overturn the present rejection and advance the case to issuance.

Dated: May 7, 2007

Respectfully submitted,

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